IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	LIEBERMAN, DANIEL	DOCKET NO.:	3998P2652
SERIAL NO.:	10/646,903	EXAMINER:	MACNEILL, E.
FILED:	08/22/2003	ART UNIT:	3767
TITLE:	METHOD AND APPARATUS FOR IRRIGATION AND DRAINAGE OF THE BRAIN'S SUBDURAL SPACE USING A PERCUTANEOUS APPROACH		

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September 28, 2007

I hereby certify that on the 28th day of September, 2007, this correspondence is being filed electronically on EFS-Web.

/s/ Jeffrey Weiss
Jeffrey Weiss

APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted in support of the Appeal in the above-identified patent application.

TABLE OF CONTENTS

REAL PARTY IN INTEREST

The present application is owned by applicant Daniel M. Lieberman, who is the real party in interest.

RELATED APPEALS AND INTERFERENCES

There are no related appeals and/or interferences pending.

STATUS OF CLAIMS

Claims on appeal: 11 and 14-27.

Canceled claims: 1-10, 12-13 and 28-33.

STATUS OF AMENDMENTS

A final rejection of Claims 11 and 14-27 was mailed on March 28, 2007. No amendments were filed subsequent to final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The independent claims involved in this appeal are Claims 11, 14, 16, 23, 24 and 25. Claim 11 is an apparatus claim. Claims 14, 16, 23, 24 and 25 are method claims.

The subject matter of Claim 11 is an apparatus used for treating subdural hematomas. The apparatus comprises a dual lumen catheter (310), which includes a drainage channel (515) and an irrigation channel (510). *See, e.g.*, p. 7, lines 2-9. The irrigation channel (510) is disposed within the drainage channel (515) and includes a plurality of tubes (561). Each tube (561) has one end coupled in fluid communication to the distal portion (514) of the irrigation channel (510), with an opposite end coupled to the drainage channel (515), so that the tubes (561) support the irrigation channel (510) inside the drainage channel (515). At the same time, the tubes (561) are dimensioned to deliver an irrigant from the irrigation channel (510) to a subdural space (125). *See, e.g.*, p. 10, lines 3-12. The dual lumen catheter (310) is designed to both irrigate and drain the brain's subdural space (125), in order to provide percutaneous drainage of a subdural hematoma (150). *See, e.g.*, p. 7, lines 10-14.

The subject matter of Claim 14 is a method for treating subdural hematomas. Insertion of the dual lumen catheter (310) into the brain's subdural space (125), in the area of a subdural hematoma (150), both drains and irrigates the subdural space (125), thereby evacuating the subdural hematoma (150). *See, e.g.*, p. 11, lines 6-9.

The subject matter of Claim 16 is a method for treating subdural hematomas. Insertion of the dual lumen catheter (310) into the brain's subdural space (125), in the area of a subdural hematoma (150), both drains and irrigates the subdural space (125). *See, e.g.*, p. 11, lines 6-9. The dual lumen catheter (310) is composed of a drainage channel (515) and an irrigation channel (510). *See, e.g.*, p. 7, lines 5-9. Subdural collection of fluid is drained from the subdural space

(125) through perforations (570) defined by the drainage channel (515) (*see, e.g.*, p. 8, lines 3-8), and the subdural space (125) is irrigated through perforations (560) defined by the irrigation channel (510) while the subdural space is drained by the drainage channel. *See, e.g.*, p. 8, lines 18-22.

The subject matter of Claim 23 is a method for treating subdural hematomas. After a burr hole (163) is drilled into the skull, a tuohy needle (205) is inserted into the brain's subdural space (125). A dual lumen catheter (310) is inserted into the tuohy needle (205). The subdural space (125) is drained of a subdural fluid collection and irrigated using the dual lumen catheter (310), and the tuohy needle (205) is removed. *See, e.g.*, p. 10, lines 20-32 and p. 11, lines 1-9 and 16-20.

The subject matter of Claim 24 is a method for treating subdural hematomas. After a burr hole (163) is drilled into the skull, a tuohy needle (205) is inserted into the brain's subdural space (125). A guide wire (207) is then advanced through the tuohy needle (205) into the subdural space (125), and the tuohy needle (205) is then removed. The subdural space (125) is drained of a subdural fluid collection and irrigated using the dual lumen catheter (310), and the guide wire (207) is removed. *See, e.g.*, p. 10, lines 20-32 and p. 11, lines 1-9.

The subject matter of Claim 25 is a method for treating subdural hematomas. A burr hole (163) is drilled into the skull. A stylette (209) is inserted into a dual lumen catheter (310) in order to give the dual lumen catheter (310) rigidity. The dual lumen catheter (310) is then inserted into the brain's subdural space (125). The subdural space (125) is drained of a subdural fluid collection and irrigated using the dual lumen catheter (310), and the stylette (209) is removed from the dual lumen catheter (310). *See, e.g.*, p. 11, lines 31-32 and p. 12, lines 1-15.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether Claim 11 is unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,605,036 to Wild?

2. Whether Claims 14 and 15-25 are unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,605,036 to Wild?

3. Whether Claims 26-27 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,605,036 to Wild in view of Dardik et al. (Journal of Vascular Surgery)?

ARGUMENT

1. Whether Claim 11 is unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,605,036 to Wild?

In the Final Office Action, the Examiner rejected Claim 11 based on Wild. Applicant respectfully submits that this rejection was in error.

Wild is directed to a surgical instrument assembly for use in endoscopic surgery, particularly endoscopic neurosurgery. In stark contrast to Wild, Applicant's invention has nothing to do with endoscopic surgery. Rather, Applicant's invention relates to the treatment of subdural hematomas, and includes procedures that do not involve endoscopy.

Wild fails to teach or reasonably suggest all aspects of Claim 11. In particular, Wild fails to disclose the feature of an "irrigation channel comprising a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel *so that the plurality of tubes support the irrigation channel inside the drainage channel* while at the same time the plurality of tubes being dimensioned to deliver an irrigant from the irrigation channel to a subdural space." *See* Claim 11 (emphasis added). While the Examiner states that "Wild's irrigation channel is taken as the group of tubes 9 and 9 (Fig 17) which are supported inside drainage channel 10 by the walls of the individual tubes 9" (Final Office Action, p. 4), Applicant respectfully submits that this is incorrect. Indeed, Wild's group of tubes 9 and 9 is separated from and not inside Wild's channel 10. *See* Wild, Fig. 17; *see also* Wild, col. 11, lines 62-66 ("The two working channels 5, 6 lie below the level of the optical channel 7 and beneath them lies the passive escape fluid channel 10. Either side of the optical channel are the two small irrigation channels 9, providing clear fluid across the objective lens.").

Accordingly, Applicant's independent Claim 11 is not anticipated under 35 U.S.C. § 102(e) by Wild. Applicant therefore respectfully submits that the rejection of Claim 11 was in error.

2. Whether Claims 14 and 15-25 are unpatentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,605,036 to Wild?

In the Final Office Action, the Examiner rejected Claims 14 and 15-25 based on Wild. Applicant respectfully submits that this rejection was in error.

a. Claims 14, 15, 18-22

With respect to Claim 14, upon which Claims 15 and 18-22, Applicant respectfully submits that Wild fails to teach each and every element claimed by Applicant, and therefore, does not anticipate this claim. Applicant notes that Claim 14 requires the insertion of a dual lumen catheter into a subdural space, followed by draining the subdural space of a subdural fluid collection with the dual lumen catheter. Wild simply does not disclose a method for draining a subdural space of a subdural fluid collection. Although Wild discusses the use of fluid, that use is for an entirely different purpose. In this regard, the use of fluid described in Wild is not for purposes of irrigating and draining a subdural space, but rather, to continuously clear debris from the optical lens of the endoscopic telescope lens. *See* Declaration Under 37 CFR § 1.132 of Dan Lieberman, M.D. (hereinafter "Lieberman Dec."), filed on February 20, 2007 and included in the evidence appendix herewith. *See also* Wild, col. 11, lines 66-67 and col. 12, lines 1-2 (noting with respect to the channels that "[t]his arrangement provides for a directional flow of clear fluid across the field collecting lens and down around the instruments, with escape of fluid and debris from underneath the working-viewing plane."); and col. 13, lines 8-10 ("Irrigation fluid is

delivered across the optical bundle as described above, so as to provide a clear view at all times."). In treating subdural hematomas, the first step must be to drain the subdural space. *See* Lieberman Dec. There is no discussion of using the Wild device for the treatment of subdural hematomas. Indeed, the only reference to the treatment of subdural hematomas included in Wild (and cited by the Examiner) concerns a discussion of prior art neurosurgery devices that stand in contrast to the endoscopic Wild device.

Further, any discussion of drainage in Wild relates to separate channels that do not comprise a dual lumen catheter. Tellingly, the words "dual" and "lumen" are absent from Wild. (The only reference in Wild to a "catheter" is in a discussion of prior art references.)

Accordingly, Applicant's independent Claim 14 is not anticipated under 35 U.S.C. § 102(e) by Wild. Applicant therefore respectfully submits that the rejection of Claim 11 was in error.

Claims 15 and 18-22 depend from Claim 14. For the same reasons that Claim 14 is not anticipated under 35 U.S.C. § 102(e) by Wild, Claims 15 and 18-22 are also not anticipated by Wild.

b. Claims 16-17

With respect to Claim 16, upon which Claim 17 depends, Applicant respectfully submits that Wild fails to teach each and every element claimed by Applicant, and therefore, does not anticipate this claim. For the same reasons that Claim 14 is not anticipated by Wild, Claims 16-17 are also not anticipated by Wild.

Applicant notes further that Wild teaches a surgical instrument for use in endoscopic surgery, and not the non-visual treatment of subdural hematomas. This difference is critical,

since an endoscope is a substantially rigid device that only allows 1-2 millimeters of insertion beneath the bone flap. Conversely, a catheter that is unencumbered by a camera, such as the dual lumen catheter described in Applicant's invention, is capable of being inserted approximately 5-10 centimeters under the bone flap. *See* Lieberman Dec. Applicant is a board certified neurosurgeon who has been in practice since 2000. *Id.* His practice includes the management of hundreds of patients with subdural hematomas. *Id.* Based on all of Applicant's expertise and experience in the field of neurosurgery generally and subdural hematomas specifically, the use of the endoscope disclosed in Wild would prevent proper entry into the subdural space for purposes of subdural evacuation of subdural fluid. *Id.*

Accordingly, Applicant's independent Claim 16 is not anticipated under 35 U.S.C. § 102(e) by Wild. Applicant therefore respectfully submits that the rejection of Claim 16 was in error.

Claim 17 depends from Claim 16. For the same reasons that Claim 16 is not anticipated under 35 U.S.C. § 102(e) by Wild, Claim 17 is also not anticipated by Wild.

c. Claim 23

With respect to Claim 23, Applicant respectfully submits that Wild fails to teach each and every element claimed by Applicant, and therefore, does not anticipate this claim. In addition to the reasons cited above, Claim 23 provides for a tuohy needle, which is inserted into the subdural space of the skull. Wild is devoid of any reference to a tuohy needle. While the Examiner refers to Wild's "outer tube 25" as a tuohy needle (Final Office Action, p. 3), Applicant respectfully submits that this is incorrect. In this regard, Wild is specifies something different for the outer tube 25, noting that "[i]n the unifunctional systems shown in FIGS. 2, 3 and 12 (a suction

instrument), 4, 5 and 13 (suction instrument) and 6, 7 and 14 (a laser applicator), the operative coupling system whereby this actuation moves the distal end 1b of the instrument comprises a generally firm but pliant outer tube 25 (e.g. of plastic) constituting an outer sheath part of the shaft 21 of the instrument." *See* Wild, col. 14, lines 1-7.

Accordingly, Applicant's independent Claim 23 is not anticipated under 35 U.S.C. § 102(e) by Wild. Applicant therefore respectfully submits that the rejection of Claim 23was in error.

d. Claim 24

With respect to Claim 24, Applicant respectfully submits that Wild fails to teach each and every element claimed by Applicant, and therefore, does not anticipate this claim. In addition to the reasons cited above, Claim 24 provides for a tuohy needle and also a guide wire, neither of which is disclosed in Wild. While the Examiner refers to "steerable push-pull wires" of Wild as a guide wire (Final Office Action, p. 3), Applicant respectfully submits that this is incorrect. In this regard, Wild specifically states that the push-pull wire is for connecting the handle to the deflector. *See* Wild, col. 2, lines 41-42. *See also* Wild, col. 4, lines 39-42 ("Operative coupling of the proximal manually operable instrument control means to the distal operative means of the instrument may be accomplished via a push-pull mechanical linkage…."). In contrast, Applicant's guide wire is for advancing a dual lumen catheter to a specific place inside the subdural space. *See* Claim 24.

Accordingly, Applicant's independent Claim 24 is not anticipated under 35 U.S.C. § 102(e) by Wild. Applicant therefore respectfully submits that the rejection of Claim 24 was in error.

e. Claim 25

With respect to Claim 25, Applicant respectfully submits that Wild fails to teach each and every element claimed by Applicant, and therefore, does not anticipate this claim. In addition to the reasons cited above, Claim 25 provides for a stylette, which is not disclosed in Wild. While the Examiner states that the "rigid telescope 2 functions in the same manner as a stylette, to provide temporary rigidity to the catheter," (Final Office Action, p. 3), Applicant respectfully submits that this is incorrect. In this regard, Wild specifically states that the rigid telescope "functions to provide an optimal view within the surgical field of the distal ends of the instruments along their entire working trajectories." *See* Wild, col. 11, lines 49-51. The rigid telescope does not provide for "temporary rigidity" and it is not designed to aid a catheter's insertion into a subdural space. These elements of method Claim 25 are simply not disclosed in Wild.

Accordingly, Applicant's independent Claim 25 is not anticipated under 35 U.S.C. § 102(e) by Wild. Applicant therefore respectfully submits that the rejection of Claim 25 was in error.

3. Whether Claims 26-27 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,605,036 to Wild in view of Dardik et al. (Journal of Vascular Surgery)?

In the Final Office Action, the Examiner rejected Claims 26-27 based on Wild as applied to Claim 14 (upon which Claims 26-27 depend) and further in view of Dardik et al. (Journal of Vascular Surgery) (hereinafter "Dardik"). Applicant respectfully submits that this rejection was in error, and that Claims 26-27 are patentable over the cited combination. In this regard, as

discussed below, Wild and Dardik, by themselves or in combination, fail to teach or reasonably suggest the subject matter of the claims rejected under 35 U.S.C. § 103(a).

As discussed above, Applicant notes that Wild is directed to a surgical instrument assembly for use in endoscopic surgery, particularly endoscopic neurosurgery. In stark contrast to Wild, Applicant's invention has nothing to do with endoscopic surgery. Rather, Applicant's invention relates to the treatment of subdural hematomas, and includes procedures that do not involve endoscopy. While the Examiner claims that Wild teaches the limitations of Applicant's dual lumen catheter, Applicant respectfully submits that this is incorrect. The deficiencies of Wild as a teaching reference with respect to Claim 14 are discussed above and are incorporated herein by reference. In addition, as the Examiner acknowledged in the Final Office Action, Wild "is silent on the duration of irrigation and drainage of the subdural hematoma." Final Office Action, p. 3. (Applicant's Claims 26 and 27 provide for, respectively, draining of a subdural space over a period of approximately three days, and irrigating of a subdural space over a period of approximately one to two days.) Dardik does not cure Wild's deficiencies.

Dardik is an article that assesses possible complications in patients following thoracoabdominal aortic aneurysm repair ("TAAA repair"), where cerebrospinal fluid ("CSF") drainage was used adjunct to the TAAA repair. *See* Dardik, Abstract. One such possible complication was the development of subdural hematomas. *Id.* The patients referred to in Dardik were being treated for TAAA, not subdural hematomas, which, according to Dardik, developed as a complication from the original purpose of the surgery. While Dardik discusses measures to be undertaken – such as the epidural placement of a bloodpatch – if such patients develop subdural hematomas, there is no teaching in Dardik regarding treatment for a subdural hematoma by Applicant's method. *See, e.g.,* Dardik, Abstract.

With respect to drains, the Examiner states that "Dardik et al teach[es] that drains are removed from patients after three days." Final Office Action, p. 3. However, the use of a drain as discussed in Dardik is entirely different from the subdural hematoma drain of Applicant's invention. In this regard, Dardik discusses certain measures that may be taken in an effort to avoid the possible complication of a subdural hematoma in patients undergoing TAAA repair and CSF drainage. *See, e.g.,* Dardik, p. 50 (noting a 67% mortality rate where patients "with acute subdural hematoma had the CSF drain popoff valve set at 5 cm H_2O" and therefore recommending "routinely setting the CSF catheter to drain at 10 cm H_2O. We also maintain the patient head position at no more than 30 degrees upright perioperatively, until the patient is alert and the mental status can be checked, to avoid potential fluctuations in CSF and cerebral perfusion pressure."). The drains to which Dardik refers are CSF drains, *not* drains for subdural hematomas. Thus, Dardik notes that "*CSF drainage* began in the operating room and continued for 3 days after surgery." Dardik, pp. 47-48 (emphasis added). *See also id.* at p. 48 ("Drains were set to allow *drainage of CSF*.... All drains were removed on the third postoperative day.") (emphasis added). Accordingly, Dardik does not teach or suggest the features recited in Applicant's Claim 26.

With respect to irrigation, there is no suggestion and, indeed, no reference at all in Dardik to such a procedure, let alone irrigation occurring over a period of approximately one to two days or irrigation of a subdural space, as Applicant's invention provides. *See* Dardik. Accordingly, Dardik does not teach or suggest the features recited in Applicant's Claims 27.

Critically, none of the cited references of Wild or Dardik make the suggestion to insert a dual lumen catheter into a subdural space for the purpose of evacuating the subdural space of a collection of fluid that has resulted in a subdural hematoma. In light of the foregoing, Wild,

Dardik, and their combination do not teach or suggest the subject matter of Claims 26-27. Accordingly, Applicant respectfully submits that the rejection of Claims 26-27 was in error.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the final rejection of Claims 11 and 14-27 was in error, and that these claims should be allowed. Accordingly, Applicant respectfully urges the Board to reverse the Examiner's final rejection of these claims.

The fees required by the filing of this appeal are tendered herewith. No additional fee or extension of time is believed to be required; however, in the event an additional fee or extension of time is required, please charge that fee or extension of time required to our Deposit Account No. 23-0830.

Respectfully submitted,

/s/ Jeffrey Weiss

Jeffrey Weiss
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CLAIMS APPENDIX

1-10. (Canceled)

11. An apparatus for use in medical procedures for treating subdural hematomas, the apparatus comprising a dual lumen catheter comprising, in combination:

a drainage channel having a proximal portion and a distal portion; and

an irrigation channel having a proximal portion and a distal portion wherein said irrigation channel being disposed inside said drainage channel, said irrigation channel comprising a plurality of tubes each having one end coupled in fluid communication to said distal portion of said irrigation channel, each opposite end of said plurality of tubes coupled to said drainage channel so that said plurality of tubes support said irrigation channel inside said drainage channel while at the same time said plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space.

12-13. (Canceled)

14. A method for treating subdural hematomas comprising, in combination, the steps of:

inserting a dual lumen catheter into a subdural space;

draining said subdural space of a subdural fluid collection with said dual lumen catheter; and

irrigating said subdural space using said dual lumen catheter.

15. The method of Claim 14 further comprising the steps of:

providing a drainage channel having a proximal portion and a distal portion;

providing an irrigation channel having a proximal portion and a distal portion;

wherein said drainage channel and said irrigation channel comprise said dual lumen catheter;

draining said subdural space of a subdural fluid collection using said drainage channel of said dual lumen catheter; and

irrigating said subdural space using said irrigation channel of said dual lumen catheter.

16. A method for treating subdural hematomas comprising, in combination, the steps of:

inserting a dual lumen catheter into a subdural space;

draining said subdural space of a subdural fluid collection with said dual lumen catheter;

irrigating said subdural space using said dual lumen catheter;

providing a drainage channel having a proximal portion and a distal portion;

providing an irrigation channel having a proximal portion and a distal portion;

wherein said drainage channel and said irrigation channel comprise said dual lumen catheter;

draining said subdural space of subdural collection fluid through perforations defined by said drainage channel; and

irrigating said subdural space through perforations defined by said irrigation channel while draining of said subdural space by said drainage channel is performed.

17. The method of Claim 16 wherein each of said drainage perforations having a diameter of between approximately .5 and .2 millimeters.

18. The method of Claim 15 further comprising the steps of:

providing a pressure valve coupled to said proximal portion of said irrigation channel; and

operating said pressure valve in order to regulate a flow of fluid irrigation from said pressure valve to said irrigation channel.

19. The method of Claim 18 further comprising the steps of:

providing an irrigation container dimensioned to retain an irrigation solution;

coupling said container to said pressure valve; and

operating said pressure valve in order to regulate a flow of fluid irrigation from said pressure valve to said irrigation channel.

20. The method of Claim 19 further comprising the step of coupling said container to said pressure valve with a luer lock fitting.

21. The method of Claim 15 further comprising the steps of:

providing a drainage container dimensioned to receive subdural collection fluid from said drainage channel;

coupling said drainage container to a proximal end of said proximal portion of said drainage channel; and

draining said subdural space of said subdural collection fluid so that said drainage container fills with said subdural collection fluid from said subdural space.

22. The method of Claim 14 further comprising the step of drilling a hole into a skull.

23. A method for treating subdural hematomas comprising, in combination, the steps of:

providing a tuohy needle;

drilling a hole in a skull;

inserting said tuohy needle into said subdural space of said skull;

inserting a dual lumen catheter into said tuohy needle;

draining said subdural space of a subdural fluid collection with said dual lumen catheter;

irrigating said subdural space using said dual lumen catheter; and

removing said tuohy needle from said subdural space.

24. A method for treating subdural hematomas comprising, in combination, the steps of:

providing a tuohy needle;

drilling a hole in a skull;

inserting said tuohy needle into a subdural space of said skull;

inserting a guide wire into said tuohy needle approximately parallel to the brain;

removing said tuohy needle from said subdural space;

advancing a dual lumen catheter along said guide wire into said subdural space;

draining said subdural space of a subdural fluid collection with said dual lumen catheter;

irrigating said subdural space using said dual lumen catheter; and

removing said guide wire from said subdural space.

25. A method for treating subdural hematomas comprising, in combination, the steps of:

drilling a hole in a skull;

inserting a stylette into a dual lumen catheter in order to give said dual lumen catheter rigidity;

inserting said dual lumen catheter into a subdural space;

draining said subdural space of a subdural fluid collection with said dual lumen catheter;

irrigating said subdural space using said dual lumen catheter; and

removing said stylette from said dual lumen catheter.

26. The method of Claim 14 wherein said draining of said subdural space occurring over approximately three days.

27. The method of Claim 14 wherein said irrigating of said subdural space occurring over approximately between 1-2 days.

28-33. (Canceled)

EVIDENCE APPENDIX

A declaration submitted in accordance with 37 C.F.R. § 1.132, filed on February 20, 2007, follows.

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Corrigan:

I, Dan Lieberman, M.D., declare as follows:

1. I am the Applicant for the patent application entitled "METHOD AND APPARATUS FOR IRRIGATION AND DRAINAGE OF THE BRAIN'S SUBDURAL SPACE USING A PERCUTANEOUS APPROACH," Ser. No. 10/646,903, filed August 22, 2003 and the inventor of the subject matter described and claimed therein.

2. I am a board certified neurosurgeon. I have been in practice since 2000. My practice includes the management of hundreds of patients with subdural hematomas, which are a routine occurrence in neurosurgical practice.

3. After a careful review of the prior art cited by the examiner, and based upon all of my years of experience in the field of neurosurgery generally and subdural hematomas specifically, the medical devices cited by the examiner in the Wild patent and Dardik et al Journal of Vascular Surgery article are not used for the treatment of subdural hematomas. There are several important differences between the techniques for suctioning a hematoma and flushing the evacuated space with fluid as compared to the techniques for endoscopy. An endoscope is a rigid device which limits entry under the bone flap to between approximately 1-2 millimeters. Conversely, a catheter that is not encumbered by a camera, such as the dual-lumen catheter that is the subject of my patent application, is capable of being inserted approximately 5-10 centimeters under the bone flap. This enormous difference is why endoscopy is not practical when treating subdural hematomas. Furthermore, endoscopic surgery can only be used in conjunction with fluid, and cannot be used in anatomical structures in which little or no fluid is present. The use of fluid described in the Wild patent is not for purposes of irrigating and draining a subdural space, but rather to continuously clear debris from the optical lens of the telescope. In treating subdural hematomas the first step must be to drain the subdural space. The Wild device cannot be used for this purpose since its use of a drainage

channel is only for purposes of removing the very fluid that is being irrigated to clear the optical lens. There is no discussion of using the Wild device for the treatment of subdural hematomas (the only reference to the treatment of subdural hematomas included in the Wild reference relates to a discussion of prior art neurosurgery devices that stand in contrast to the endoscopic Wild device).

4. I further declare that all statements made herein are of my own knowledge and all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the above-referenced application and any patent issuing therefrom.

FURTHER DECLARANT SAYETH NOT.

Dan Lieberman

Dan Lieberman, M.D.

2/20/07

Date

RELATED PROCEEDINGS APPENDIX

None.